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KCI

# 510(k) SUMMARY

MAR - 4 2009

## Product Name: Open Abdomen Negative Pressure Therapy System

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| **Date prepared** | November 12, 2008 |
| **510(k) owner** | KCI USA, Inc. |
| **Name** | KCI USA, Inc. |
| **Address** | 6203 Farinon Dr., San Antonio, TX 78249 |
| **Fax number** | (210) 255-6727 |
| **Name of contact person** | Christy Hubbard Oviatt |
| **Name of the device** | Open Abdomen Negative Pressure Therapy System |
| **Trade or proprietary name** | To be determined |
| **Common or usual name** | Negative Pressure Therapy Unit |
| **Classification name** | JCX |
| **Device description** | The Open Abdominal Negative Pressure Therapy System is designed for the application of negative pressure therapy for temporary bridging of the abdominal wall for patients with an open abdominal wound due to trauma, abdominal surgery, infection and/or abdominal compartment syndrome. It is comprised of a negative pressure therapy unit, a canister and the currently cleared and marketed V.A.C.® Abdominal Dressing. |
| **Legally marketed device(s) to which equivalence is claimed** | • The V.A.C.® Abdominal Dressing which is currently cleared under 510(k) K022011.<br>• The Open Abdominal Negative Pressure Therapy unit and its associated canister represent design modifications of the V.A.C.® ATS Therapy unit which was most recently included in 510(k) K062227 for the V.A.C.® Therapy System. |

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| **How the device functions** | • The system applies negative pressure to the open abdominal wound to create an environment for delayed primary closure by reducing edema, and by removing exudate and infectious material under the influence of continuous negative pressure.<br>• The therapy unit monitors and maintains target pressure and alarms as needed to help assure target pressure is maintained and constant therapy is delivered for optimal wound management. |
| **Scientific concepts that form the basis for the device** | Negative pressure applied to an open abdominal wound creates a pressure differential to actively remove fluids and reduce edema. Edema is reduced by removing excessive interstitial fluid that has accumulated within the tissues. General reduction of edema assists in primary fascial closure of the abdominal wall. |
| **Device design** | • The reusable negative pressure therapy unit uses a brushless double diaphragm motor driven pump to generate negative pressure.<br>• A non-sterile canister collects the removed wound exudate.<br>• A tubing set conducts negative pressure to the open abdominal wound and transfers exudate to the canister.<br>• The V.A.C.® Abdominal Dressing is a specialty dressing, supplied sterile for single use only. It is double pouched and packaged as a kit with<br>o One internal contact layer<br>o Two 16 mm outer layer open-cell foam pieces<br>o Four V.A.C.® Drapes<br>o One T.R.A.C.™ Pad Assembly |
| **Safety Features** | The safety features of the therapy unit include a tubing blockage alarm, a full or missing canister alarm, low battery alarm, and an alarm to indicate a leak in the seal of the V.A.C.® Abdominal Dressing. Additionally, a hydrophobic membrane filter is a part of each canister to prevent fluid and microbial ingress into the therapy unit. |
| **Material used** | • V.A.C.® Abdominal Dressing is comprised of a polyurethane contact layer, polyurethane open cell foam, and polyurethane film with acrylic adhesive drape (See K022011).<br>• Open Abdominal Negative Pressure Therapy unit is housed in a hard thermoplastic shell.<br>• The canister is made from general purpose polymer materials. |

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| **Intended use of the device** | The V.A.C. Open Abdomen Negative Pressure Therapy System is a specialty system indicated for temporary bridging of abdominal wall openings where primary closure is not possible and or repeat abdominal entries are necessary. The Intended Use of this system is for use in open abdominal wounds, with exposed viscera, including but not limited to abdominal compartment syndrome.<br><br>The intended care setting is the acute hospital setting: in trauma, general and plastic surgery wards. The abdominal dressing will most often be applied in the operating theater. |
| **Differences in intended use from the predicate(s)** | The intended use of the Open Abdomen Negative Pressure System is the same as the intended use of the V.A.C.® Abdominal Dressing. |
| **Summary of the technological characteristics of the device compared to the predicate device** | The new Open Abdomen Negative Pressure Therapy Unit is a new therapy unit for use with the V.A.C.® Abdominal Dressing. The new therapy unit is a simpler design using updated technology. The fundamental operating principles have not changed. It is a smaller and lighter unit with therapy settings relevant to those required for open abdominal wound applications. |
| **Summary of nonclinical tests** | The Open Abdomen Therapy unit was evaluated under a number of performance tests to assure performance and conformance to design specifications. |
| **Conclusions drawn from the nonclinical and clinical tests that demonstrate that the device is as safe, as effective, and performs as well as or better than the predicate device** | The performed testing documents that the Open Abdomen Therapy System and the V.A.C.® ATS Therapy system with the V.A.C.® Abdominal dressing are equivalent in terms of technology and performance specifications for the delivery of negative pressure to the open abdomen. |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 7 2009

KCI USA, Inc.
% Ms. Christy Oviatt
6203 Farinon Drive
San Antonio, Texas 78230

Re: K083357
Trade/Device Name: Open Abdomen Negative Pressure Therapy System
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered Suction Pump
Regulatory Class: II
Product Code: OMP
Dated: February 6, 2009
Received: February 9, 2009

Dear Ms. Oviatt:

This letter corrects our substantially equivalent letter of March 5, 2009.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not

limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K083357

# INDICATIONS FOR USE

510(k) Number (if known): K083357

Device Name: Open Abdomen Negative Pressure Therapy System

Indications for Use:

The V.A.C. Open Abdomen Negative Pressure Therapy System is a specialty system indicated for temporary bridging of abdominal wall openings where primary closure is not possible and or repeat abdominal entries are necessary. The Intended Use of this system is for use in open abdominal wounds, with exposed viscera, including but not limited to abdominal compartment syndrome.

The intended care setting is the acute hospital setting: in trauma, general and plastic surgery wards. The abdominal dressing will most often be applied in the operating theater.

Prescription Use ____X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause for MXM 3/5/2009

**(Division Sign-Off)**
**Division of General, Restorative, and Neurological Devices**



*(Posted November 13, 2003)*

**510(k) Number** K083357